

2121  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Henning, et al.

Group No.: 2121

Serial No.: 10/023,501

Examiner:

Filed: 12/17/2001

For: "Method for Increasing Clinical Specificity When Detecting Tumors and Their Precursor Stages by Simultaneously Measuring at Least Two Different Molecular Markers"

CERTIFICATION OF MAILING UNDER 37 C.F.R. 1.8(a)

I hereby certify that this correspondence and any papers referred to as attached are being deposited, on the date shown below, with the United States Postal Service, with sufficient postage, as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: AUG 01 2002

*Mariellen Chaykin*  
Signature of Person Certifying

RECEIVED  
AUG 08 2002

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

Technology Center 2100

TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))

Dear Sir:

Applicants wish to cite for the record in the above-identified application the references shown on the accompanying copy of PTO form 1449.

**IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING  
INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement transmitted herewith is being filed **before** the mailing date of the first Office action on the merits.

**FEE PAYMENT**

Applicants believe that no fees are due with this submission. However, the Commissioner is hereby authorized to charge any fees that may have been overlooked but that are required to Deposit Account 13-3372. Additionally, please credit any overpayment to the same account.

Respectfully submitted,

*Susan M. Pellegrino*

Susan M. Pellegrino  
Attorney for Applicant(s)  
Bayer Corporation  
400 Morgan Lane  
West Haven, CT 06516

Reg. No. 48,972

Telephone: (203) 812-6450

Date: AUG 01 2002

RECEIVED



For O-1449  
(Modified)

U.S. Department of Commerce  
Patent and Trademark Office

Serial No.  
10/023,501

Group Art Unit  
2121

Filing Date  
12/17/2001

Atty. Docket No.  
Le A 35 012

**SUPPLEMENTAL  
INFORMATION DISCLOSURE CITATION**

Applicant(s) Henning, et al.

**RECEIVED**

AUG 08 2002

Technology Center 2100

**U.S. PATENT DOCUMENTS**

| * |           | DOCUMENT NO. |   |   |   |   |   |   |  | DATE<br>MM/DD/YY | NAME            | CLASS | SUB-<br>CLASS | FILING DATE<br>IF<br>APPROPRIATE |
|---|-----------|--------------|---|---|---|---|---|---|--|------------------|-----------------|-------|---------------|----------------------------------|
|   | <b>U3</b> | 6            | 0 | 0 | 5 | 2 | 5 | 6 |  | 12/21/99         | McGlynn, et al. | 250   | 559.4         | 02/12/98                         |
|   | <b>U4</b> | 5            | 5 | 4 | 4 | 6 | 5 | 0 |  | 08/13/96         | Boon, et al.    | 128   | 632           | 02/14/94                         |

**FOREIGN PATENT DOCUMENTS**

|  |  | DOCUMENT NO. |  |  |  |  |  |  |  | DATE<br>DD/MM/YY | COUNTRY | PRIMARY<br>CLASS | SUB-<br>CLASS | TRANSLATION |     |    |
|--|--|--------------|--|--|--|--|--|--|--|------------------|---------|------------------|---------------|-------------|-----|----|
|  |  |              |  |  |  |  |  |  |  |                  |         |                  |               |             | YES | NO |
|  |  |              |  |  |  |  |  |  |  |                  |         |                  |               |             |     |    |

**OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)**

|           |  |
|-----------|--|
| <b>R1</b> | Williams, G., Romanowski, P., Morris, L., Madine, M., Mills, A., Stoeber, K., Marr, J., Laskey, R., Coleman, N., "Improved Cervical Smear Assessment Using Antibiotics Against Proteins That Regulate DNA Replication", Proc. Natl. Acad. Sci. USA, <u>95</u> : 14932-14937 (Dec., 1998)         |
| <b>R2</b> | Cuzick, J., "Human Papillomavirus Testing For Primary Cervical Cancer Screening", JAMA, <u>283</u> : 108-109 (Jan., 2000)  |
| <b>R3</b> | Tervahauta, A., Syrjanen, S., Mäntylä, R., Syrjanen, K., "Detection of p53 Protein and Ki-67 Proliferation Antigen in Human Papillomavirus (HPV)-Positive and HPV-Negative Cervical Lesions by Immunohistochemical Double-staining", Cytopathology, <u>5</u> : 282-293 (1994)                    |
| <b>R4</b> | Boon, M., Beck, S., Kok, L., "Semiautomatic PAPNET Analysis of Proliferating (MiB-1-Positive) Cells in Cervical Cytology and Histology", Diag. Cytopathology, <u>13</u> : 423-428 (1995)   |
| <b>R5</b> | Sawaya, G., Washington, A., "Cervical Cancer Screening: Which Techniques Should Be Used and Why?", Clin. Obstetrics and Gynecology, <u>42</u> : 922-938 (1999)   |
| <b>R6</b> | Sano, T., Oyama, T., Kashiwabara, K., Fukuda, T., Nakajima, T., "Immunohistochemical Overexpression of p16 Protein Associated with Intact Retinoblastoma Protein Expression in Cervical Cancer and Cervical Intraepithelial Neoplasia", Path. Int., <u>48</u> : 580-585 (1998)                   |
| <b>R7</b> | Gómez, F., Roldán, M., Corcuera, M., Picazo, A., Muñoz, E., Alonso, M., "Simultaneous Detection of Antigens and Specific DNA Sequences of Human Papillomavirus in Uterine Cervical Biopsy Specimens. Description of a Double-Labeling Technique", Eur. J. Histochem., <u>41</u> : 255-259 (1997) |
| <b>R8</b> | Stoler, M., "Advances in Cervical Screening Technology", Mod. Pathol., <u>13</u> : 275-284 (2000)  |
| <b>R9</b> | Leek, R., Kaklamani, L., Pezzella, F., Gatter, K., Harris, A., "bcl-2 in Normal Human Breast and Carcinoma, Association With Oestrogen Receptor-Positive, Epidermal Growth Factor Receptor-Negative Tumours and In   |

EXAMINER

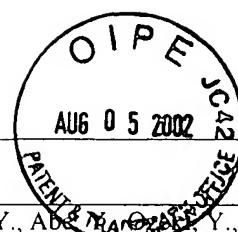
**RECEIVED**

DATE CONSIDERED

\* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEP 17 2002

TECHNOLOGY CENTER R3700



|  |     |  |
|--|-----|--|
|  |     | Situ Cancer", Br. J. Cancer, 69: 135-139 (1994)  |
|  | R10 | Oshika, Y., Nakamura, M., Tokunaga, T., Fukushima, Y., Abe, Y., Yamada, Y., Yamazaki, H., Tamaoki, N., Ueyama, Y., "Multidrug Resistance-Associated Protein and Mutant p53 Protein Expression in Non-Small Cell Lung Cancer", Mod. Pathol., 11: 1059-1063 (1998) |
|  | R11 | Kraeft, S., Sutherland, R., Gravelin, L., Hu, G., Ferland, L., Richardson, P., Elias, A., Chen, L., "Detection and Analysis of Cancer Cells in Blood and Bone Marrow Using a Rare Event Imaging System", Clin. Cancer Research, 6: 434-442 (Feb., 2000)          |
|  | R12 | Reiner, A., Neumeister, B., Spona, J., Reiner, G., Schemper, M., Jakesz, R., "Immunocytochemical Localization of Estrogen and Progesterone Receptor and Prognosis in Human Primary Breast Cancer", Cancer Research, 50: 7057-7061 (Nov., 1990)                   |
|  | R13 | Mokbel, K., Parris, C., Ghilchik, M., Williams, G., Newbold, R., "The Association Between Telomerase, Histopathological Parameters, and KI-67 Expression in Breast Cancer", Am. J. Surgery, 178: 69-72 (1999)  |

RECEIVED

AUG 08 2002

Technology Center 2100

RECEIVED  
SEP 17 2002  
TECHNOLOGY CENTER R3700

| EXAMINER  | DATE CONSIDERED |
|---|-----------------|
| * EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |